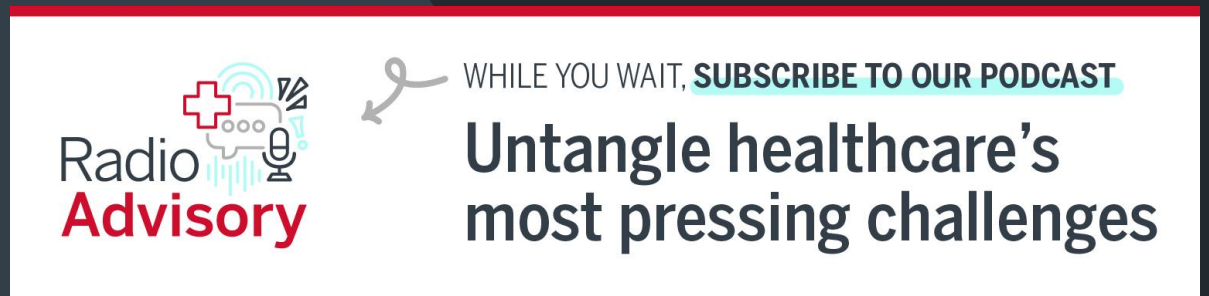
Advisory Board

Unpacking the interplay between innovation and accessibility



ABOUT

Solomon Banjo, MPP

Managing Director, Life Sciences Research

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LinkedIn

Solomon leads Advisory Board's pharmaceutical and medical device manufacturers research. His team focuses on the ways medical evidence is used and sourced are evolving.

He studies the ripple effects these changes can have on stakeholders and shared objectives like improving clinical decision-making, elevating the patient voice, and making data-informed tradeoffs.

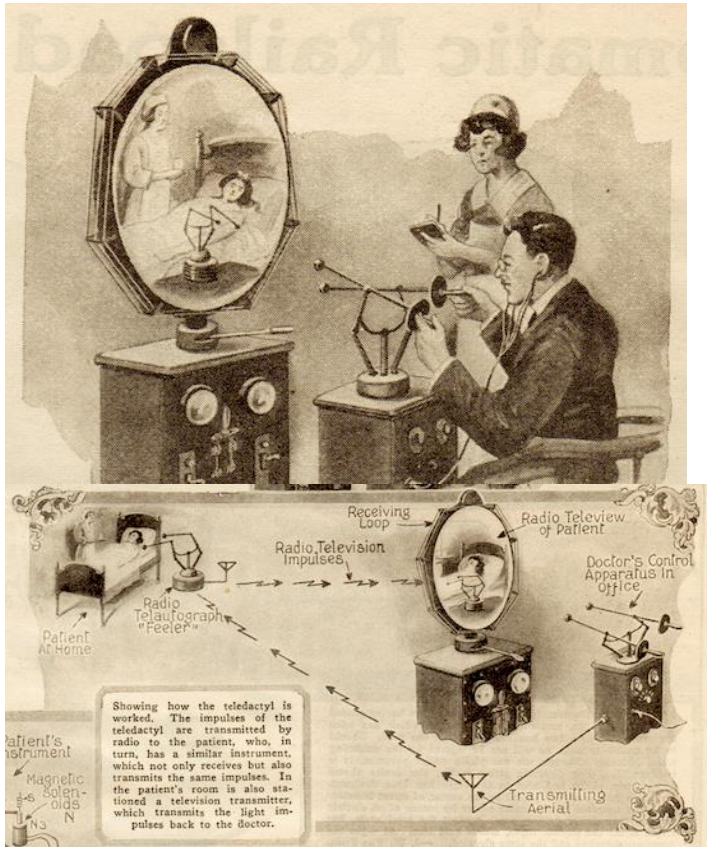
Solomon previously led research for domestic and international healthcare providers focused on ambulatory strategy and high-risk patient management.

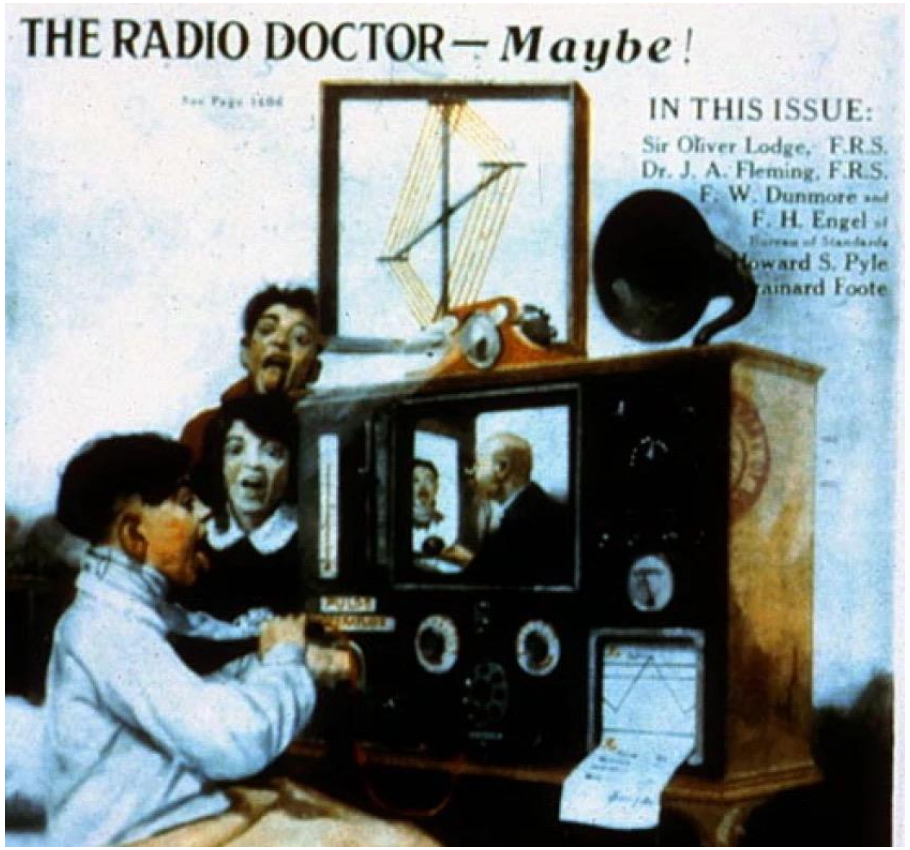
Areas of expertise

RWD, clinical decision-making, population health, medical value, service line strategy, life sciences

The future of healthcare 100 years ago

Magazine covers from 1924/25





Source: "The Radio Doctor", World Radio History; M. Novak, "Telemedicine predicted in 1925", *Smithsonian Magazine*, Mar 12, 2012.

The innovation landscape today

Diagnostics

Precision diagnostics
- Pharmacogenomics
- Biomarker testing
- Digital pathology
- Liquid biopsy
- AI/ML[1] enhanced imaging
- Microbiome testing
- Companion diagnostics
- Single & Multi-disease panels
- Next-gen sequencing

Out of the lab
- At-home diagnostic kits
- Point-of-care diagnostics

Treatment

Pharmaceuticals
- Cell and gene therapies
- Breakthroughs in Alzheimer's treatment
- Weight management drugs

Surgical advancements
- AI-enhanced surgery
- Surgical robotics
- Bioabsorbable stents
- Leadless pacemakers

Other
- Digital therapeutics
- Theranostics

Management

Wearable consumer technology
- Smartwatches
- Fitness trackers

Remote patient monitoring
- Continuous glucose monitoring
- Digital heart rate and blood pressure monitors
- Electronic skin patches

Digital management platforms
- Drug/surgery companion apps

Enabling technology

Artificial intelligence

3D printing

Extended reality
- AR[2]
- VR[2]
- MR[2]

Internet of things
- Mobile health apps
- Connected medical devices

1. Artificial Intelligence and Machine Learning.
2. Augmented Reality, Virtual Reality, Mixed Reality.

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Past eras of innovation focused on using tech at scale

Snapshot of Advisory Board's first innovation research

RESEARCH IN BRIEF

- Released in 2002 and reported on the "Decade of the Device"
- Covered a wave of new technologies that replaced current practice for material gains in efficiency and outcomes
- Focused on concept that innovations had the potential to provide major clinical gains to large patient populations
- Continued assumption that patients with the same condition should largely be treated in the same way

Healthcare industry responds by advancing standardization practices

Care delivery

Standardized care pathways and leveraged technology in as many care pathways as possible to achieve scale

Payers

Established additional prior authorization to ensure treatment adhered to standardized care guidelines

Manufacturers

Developed innovations that could be marketed to and used by large patient populations

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Our current future has been a long time coming

Advancements in healthcare's view of quality

2001 — IoM's[1] "*Crossing the Quality Chasm*" is released

2010 — Patient Protection and Affordable Care Act is signed into law

2014 — FDA establishes "Patient-Focused Drug Development" Program

2017 — 21st Century Cures Act is signed into law

2020 — Commission on Cancer releases updated standards, requiring survivorship program

2023 — Biden administration relaunches Cancer Moonshot, facilitating advancements in precision medicine, biomarker research, and companion diagnostic, among others

Advancements in technology impacting healthcare

2003 — Human Genome Project is completed

2012 — Apple releases the iPhone's Health App, increasing number of individuals regularly tracking health data

2017 — FDA approves first CAR-T cell therapy

2022 — ChatGPT gains 100 million users in two months

2020s kicks off era of bespoke care

1. Institute of Medicine.

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Enter the era of bespoke care

Components of the era of bespoke care

Patient ROI
Shifts the definition of quality and value to the individual level

Personalization
Measures and understands the individual patient's characteristics and preferences

Upstream cost trade-offs
Requires higher costs in the short term with the promise of lower long-term costs

Increased complexity to deliver
Requires high level of skill and time from clinicians to deliver

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Today’s innovation can have incredible impacts on patients in a perfect world…

New York Times

“A cancer trial’s unexpected result: Remission in every patient”

Modern Healthcare

“3D printing helps NY children’s hospital customize assistive tech”

USA Today

“‘It’s brought back so much hope’: Paralyzed central KY deputy wants to be part of Neuralink trials”

New York Post

“Apple Watch saved grandma’s life by catching heart condition”

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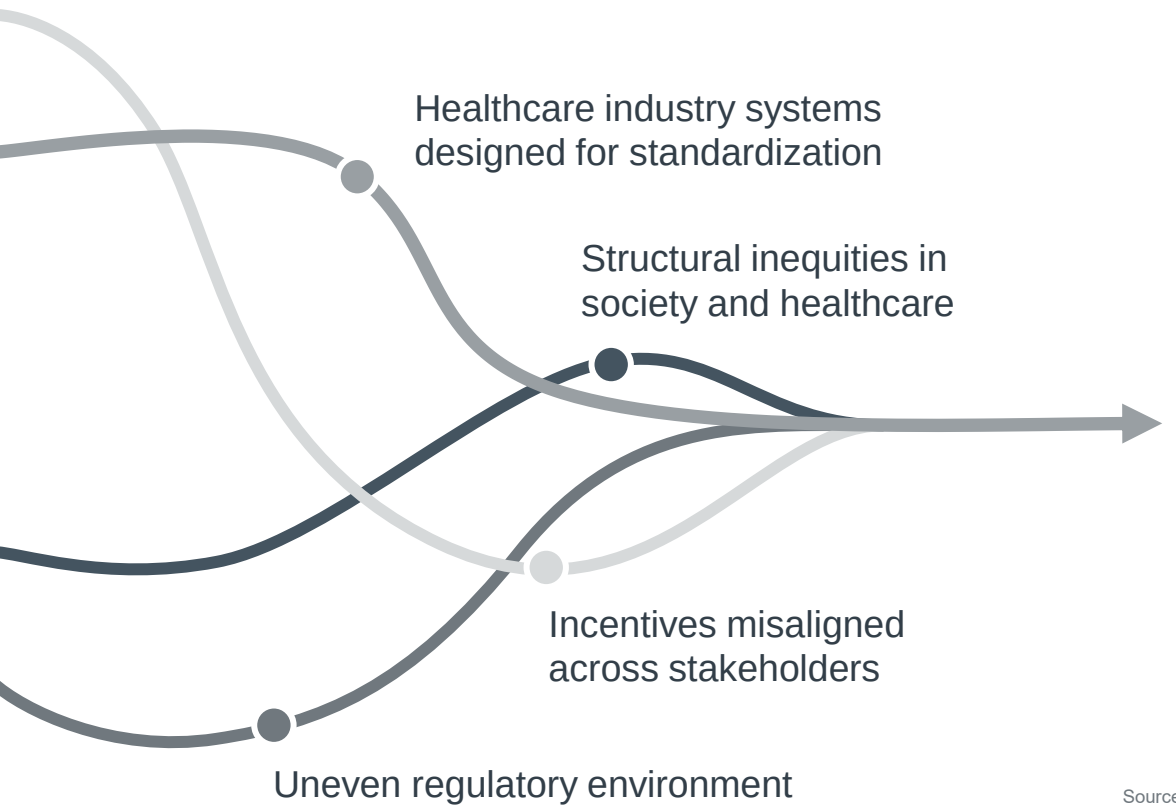
…but we don't live in a perfect world

Factors limiting access to innovation



4% Percent of genome-wide association cancer-related studies that focus on populations other than those of European or Asian descent

25% Percent of Americans who may not have technology, internet, or digital literacy needed to participate in virtual visits

38% Percent of Americans reporting they or family members postponed treatment due to costs in 2022

33% Increase in monthly mortality among Medicare enrollees facing a $10 increase in cost-sharing

Source: 2023 Benefit Design Report, PSG, June 2023; "Addressing Equity in Telemedicine for Chronic Disease Management During the Covid-19 Pandemic", *New England Journal of Medicine*, May 4, 2020; "Lack Of Diversity In Genomic Databases Is A Barrier To Translating Precision Medicine Research Into Practice", Health Affairs, May 2018; "Record High in U.S. Put Off Medical Care Due to Cost in 2022", Gallup, Jan 17, 2023; "The Use of Medicines in the U.S. 2022: Spending and Usage Trends and Outlooks to 2026" IQVIA Institute, April 2022; Chandra, A., et al.,., "The Health Costs of Cost-Sharing," National Bureau of Economic Research, Working Paper, 2021; Montero, A, et al., "Americans' Challenge with Health Care Costs, " Kaiser Family Foundation, 2022

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FACT

Clinical and technological innovation exist that allows for bespoke care

FICTION

Patients and providers will be able to access that innovation in an affordable and equitable way

Four dynamics we'll need to address

Appropriate use

Establish a clear and timely understanding of an innovation's benefit and when that benefit leads to high-quality care

Payment models

Determine payment rates and models that account for multiple definitions of value both in the short and long term

Clinician knowledge

Encourage clinicians to leverage innovation while ensuring they have the education and support to build skills needed to do so

Data privacy

Use individual patients' data and preferences to personalize care while making sure that patients trust how their information is being used

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Healthcare infrastructure not designed for today's innovations

Time it takes for the AMA[1] to assign a new CPT[2] code

18-24 months

In that time, there will likely be:

- 8-10k New genetic tests entering the market
- 25-35 New FDA-approved cell and gene therapies
- ~300 New FDA-approved AI algorithms

1. American Medical Association.
2. Current Procedural Terminology.

Source: "Applying for a New CPT Code", MDI Consultants; "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices", FDA, Oct 5, 2022; "Statement from FDA on new policies to advance development of safe and effective cell and gene therapies", FDA, Jan 15, 2019; "The Current Landscape of Genetic Testing", Concert Genetics, 2018.

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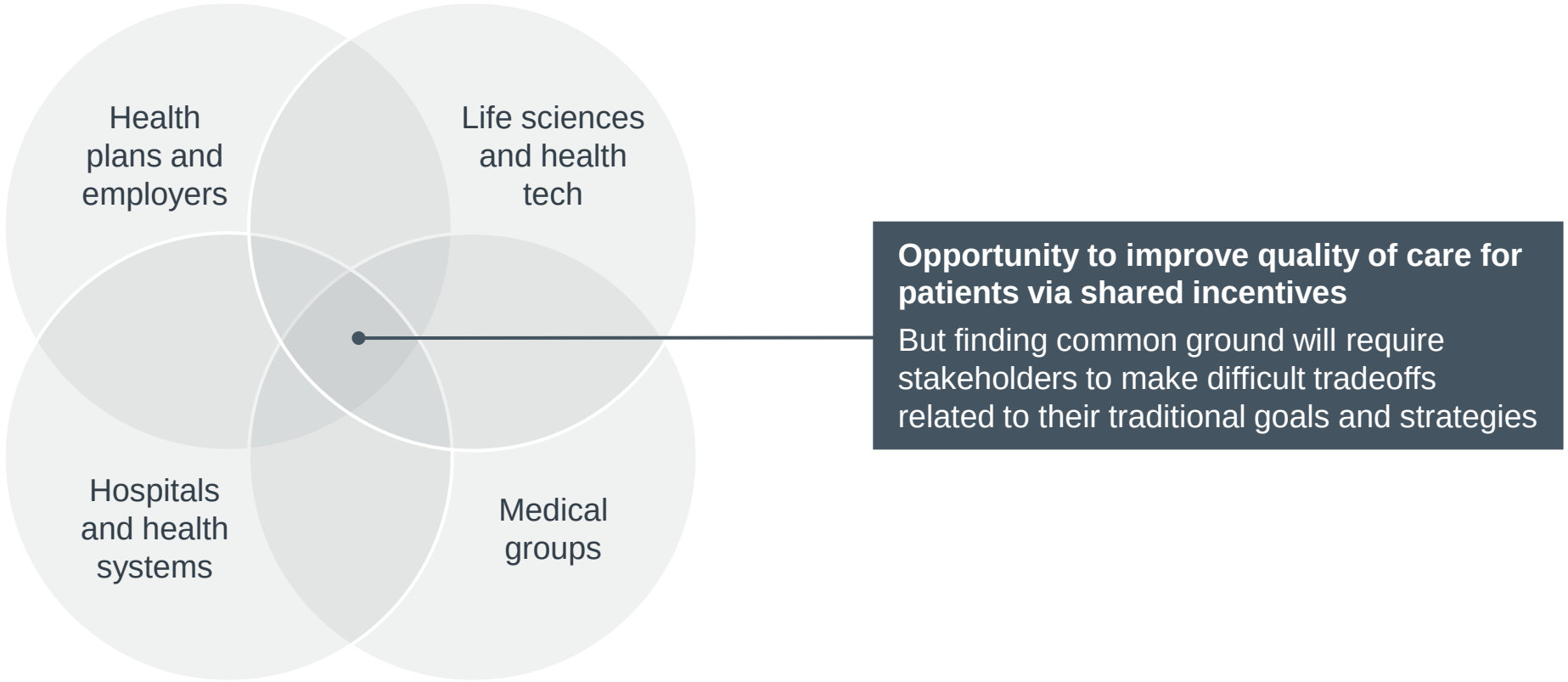
Finding the right tuning won’t be easy

Industry stakeholder goals and incentives



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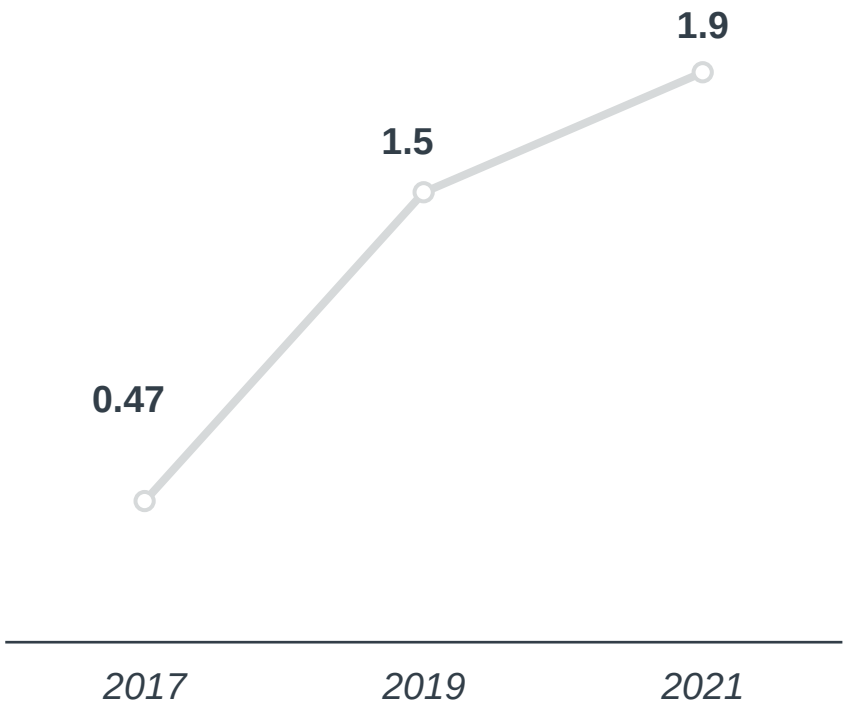
New innovations inconsistently applied

Growth in genetic testing

Medicare Part B spend on genetic tests
(in billions)



Environment exists for excessive use

10+

Different genetic tests received by more than **67,000 Medicare beneficiaries** from 2016-2019

38

Number of genetic tests one Medicare beneficiary received in 2018/2019 – some of which were the **same test performed six or more times**

Of genetic tests were inappropriate in study from San Diego Naval Medical Center

Source: "Genetic tests often overused and misinterpreted, sometimes with tragic consequences", *The San Diego Union Tribune*, May 5, 2017; "Trends in genetic tests provided under Medicare Part B Indicate Areas of Possible Concern", Office of Inspector General, Dec 2021.

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TCOC[1] and patient centricity not mutually exclusive

MSK[2] and Carrum Health aligned visions and capabilities to offer cancer care bundles to employers

FINDING A PARTNER WITH SHARED GOALS

MSK

sought to align financial incentives while doing what's best for patients

Carrum

wanted to offer higher value to the employers they serve

Both organizations

spent the prior 5-6 years working independently on cancer care bundles

DESIGNING SOLUTIONS THAT PROMOTE QUALITY AND VALUE

DETERMINING PRICE

1.5 years spent contracting

MSK had dedicated team studying costs to determine bundle pricing

Carrum provided real-world data to inform cost analyses

DEFINING SERVICES

2 -year bundles for non-metastatic breast and thyroid cancer patients

MSK provides cancer care services for a single upfront payment from employers

Carrum

- provides patient with case manager and digital communication platform
- sends MSK all relevant patient records
- coordinates between MSK and local oncologists
- organizes patient travel

1. Total cost of care.
2. Memorial Sloan Kettering Cancer Center.

Source: Carrum Health, San Francisco, CA; Memorial Sloan Kettering, New York, NY.

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Bundle options offer value to variety of purchasers

Guidance bundle

Virtual connection between MSK specialists, local oncology providers, and patients

- Includes:
  - Genetic testing and other diagnostic workup
  - Second opinions
  - Treatment guidance
  - Ongoing collaboration with patient's local oncologist
- Relies on Carrum's digital communication platform

Treatment bundle

In-person cancer-related care received at MSK

- Multiple bundles correspond with different treatment pathways
  - 5 basic breast cancer bundles depend on elements of treatment (e.g., surgery, radiation, chemo) and whether cancer is HER2+
  - 3 thyroid cancer bundles dependent on treatment decisions
- Includes drugs, ED visits due to chemotherapy toxicity, and any other cancer-related care

Hybrid bundle

Combination of guidance bundle and excision surgery treatment bundle

- Patients receive excision surgery at MSK
- Chemotherapy, radiation therapy, and other cancer treatment is received locally

KEY MILESTONE

Roll-out started in May 2021 with three employers

Source: Carrum Health, San Francisco, CA; Memorial Sloan Kettering, New York, NY.

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Considerations for defining benefit, value, and appropriate use

For the healthcare ecosystem to **establish a clear understanding of an innovation's benefit and when that benefit leads to high-value care,** industry leaders consider:

Payers

- Which metrics will define product performance
- How to limit use when innovation is not indicated and maximize use when it is

Care delivery

- If innovation provides options for care to patients that previously did not have an opportunity for treatment
- The appropriate level of variation in care protocols without compromising patient safety

Manufacturers

- Which metrics can best articulate better patient need or value
- How to gain buy-in on new metrics that better capture patient value
- How measuring certain metrics impacts costs, timeline, and targets for development and testing

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New therapies strain payment models

Cell and gene therapy applications expanding

1.09M

Estimated patients treated by gene therapy between 2020 and 2035

$25.3B

Estimated annual spend on gene therapy in 2026

0.5%

Predicted gene therapy spend as a percent of estimated national health expenditure in 2026

Why paying for these drugs is difficult

01 **Performance uncertainty** of these expensive treatments in the long term

02 **Actuarial uncertainty** given the patient populations these treatments impact are so small

03 **Payment timing** for treatments that provide a lifetime's worth of value if patients switch payers across their lifetime

Source: Advisory Board Gene and Cell Therapy Forecaster Tool; "Estimating the Financial Impact of Gene Therapy in the U.S.", NBER, April 2021; "Projected National Health Expenditure Data", CMS.

Advisory Board interviews and analysis.

12-18 months is not the default for medical value

Align value end points to meaningful time-to-impact horizon

	Temporary (<12 months)	Average (12-18 months)	Long-term (2-5 years)	Lifetime (5+ years)
PAYER PROFILE	State sponsored and operated	Large national, Blues	Regional not-for-profit, Blues	Health system-sponsored health plan
BUSINESS LINES	• Public exchanges • COBRA • Medicaid (states with limited coverage)	• Employer-sponsored plans • Employer-sponsored/ individual plans in growing metro regions	• Medicaid (states with limited mobility; disability) • Accountable care organizations • Clinically integrated networks	• Medicare Advantage • Rural/suburban provider-sponsored plans
VALUE ENDPOINTS	**Which value endpoints align with annual budgets and contracts?**		**Which value endpoints impact individual and population-level total cost of care?**	

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For high-cost drugs, payment will hinge on… *outcomes*

Major recent outcomes-based contracting arrangements for drugs

	Large population High initial cost		Niche segment High initial cost		Large population High ongoing cost		
Payer	**Oklahoma Medicaid**	**Harvard Pilgrim**	***TBD***	**Aetna**	**UPMC**	**Harvard Pilgrim**
Drug	Orbactiv (Melinta)	Luxturna (Spark)	Zynteglo (Bluebird)	Entresto (Novartis)	Brillinta (AstraZeneca)	Repatha (Amgen)
Key outcome metric	Net neutral cost (including avoided hospitalization)	Light sensitivity test score	Resumed blood transfusions	Heart failure admissions reductions	Heart attack or unstable angina	Heart attack or stroke
Penalty type	Additional rebate	Additional rebate	Waive remaining installments	Additional rebate	Additional rebate, additional fee (for positive result)	Full refund

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Considerations for redesigning reimbursement

For the healthcare ecosystem to **determine payment rates and models that account for multiple definitions of value,** industry leaders consider:

Payers

- How to manage financial and performance risk
- How to align payment models with value timelines
- Developing solutions for new product categories

Care delivery

- Administrative and data resources needed to monitor and measure outcomes that could impact payment
- How to ensure clinicians are paid appropriately for delivering services that leverage innovative products

Manufacturers

- Additional investments in data and staff needed to implement alternative payment models with payers and/or providers
- Balancing data needed to support adoption with future uncertainty
- Designing solutions that work for patients from various backgrounds

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Clinicians face increasing complexity in decision-making

Personalized medicine becoming more clinically possible, but operationally difficult

Clinicians struggle to assess numerous treatment options

68% of physicians report feeling overwhelmed by the amount of information to keep up with, 2022

Non-clinical factors block patients from best treatment

Patients living within 60 miles of sites offering gene therapy are more than 2x as likely to receive therapy, 2022

Care requires coordination across specialties and sites

Leqembi[1] patients require:

- *Referral to neurologist to assess risk of complications*
- *Regular MRIs before and during treatment*
- *Tracking data in CMS registry*

LEARNINGS FROM MEDICAL ONCOLOGY

Infrastructure we're likely to see more of

- Organizational governance for formulary decisions, prescribing guidelines, and clinical pathways
- Emphasis on real world evidence
- Clinical decision-support technology
- Shared decision-making tools
- Expert consults and hardwired referral pathways
- Patient navigation and coordination

1. Medication used to treat Alzheimer's disease.

See additional sources slide for sources.

Advisory Board interviews and analysis.

We need to ask the right questions to deploy tech

~~"What technology do we need?"~~  "What do we need to do?"

How AI enabled Castell to improve workflows

CASE EXAMPLE

Castell

An Intermountain Health company • Salt Lake City, Utah

- Castell used Intermountain's existing partnership with Notable to introduce "digital assistants" powered by AI
- Instead of care coordinators manually searching medical records, the digital assistants surface provider recommendations in a central location of the EHR that the care coordinator can easily access

70% reduction in time spent per chart, which is approximately 1.7 minutes saved per chart

Data spotlight

75% Reduction in daily time spent reviewing charts for each care coordinator, decreasing from four hours to one hour

47 Additional FTEs would have been required without digital assistants, saving the system an estimated $2.8M annually

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Considerations for supporting clinician decision-making

For the healthcare ecosystem to **encourage clinicians to leverage innovation, while ensuring they have the education and support needed to do so**, industry leaders consider:

Payers

- Establishing benefit design and appropriate use for the spectrum of innovation adopters
- Exploring new data types to share with clinicians

Care delivery

- How to transform workflows to maximize value of tools while reducing unnecessary steps
- Ripple effects of adopting new tools both internally and externally

Manufacturers

- The best way to deliver educational and support services that help clinicians use products appropriately
- How to generate and share trustworthy data that meets clinician and patient needs

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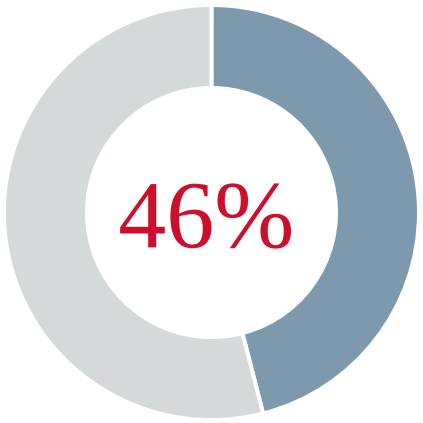
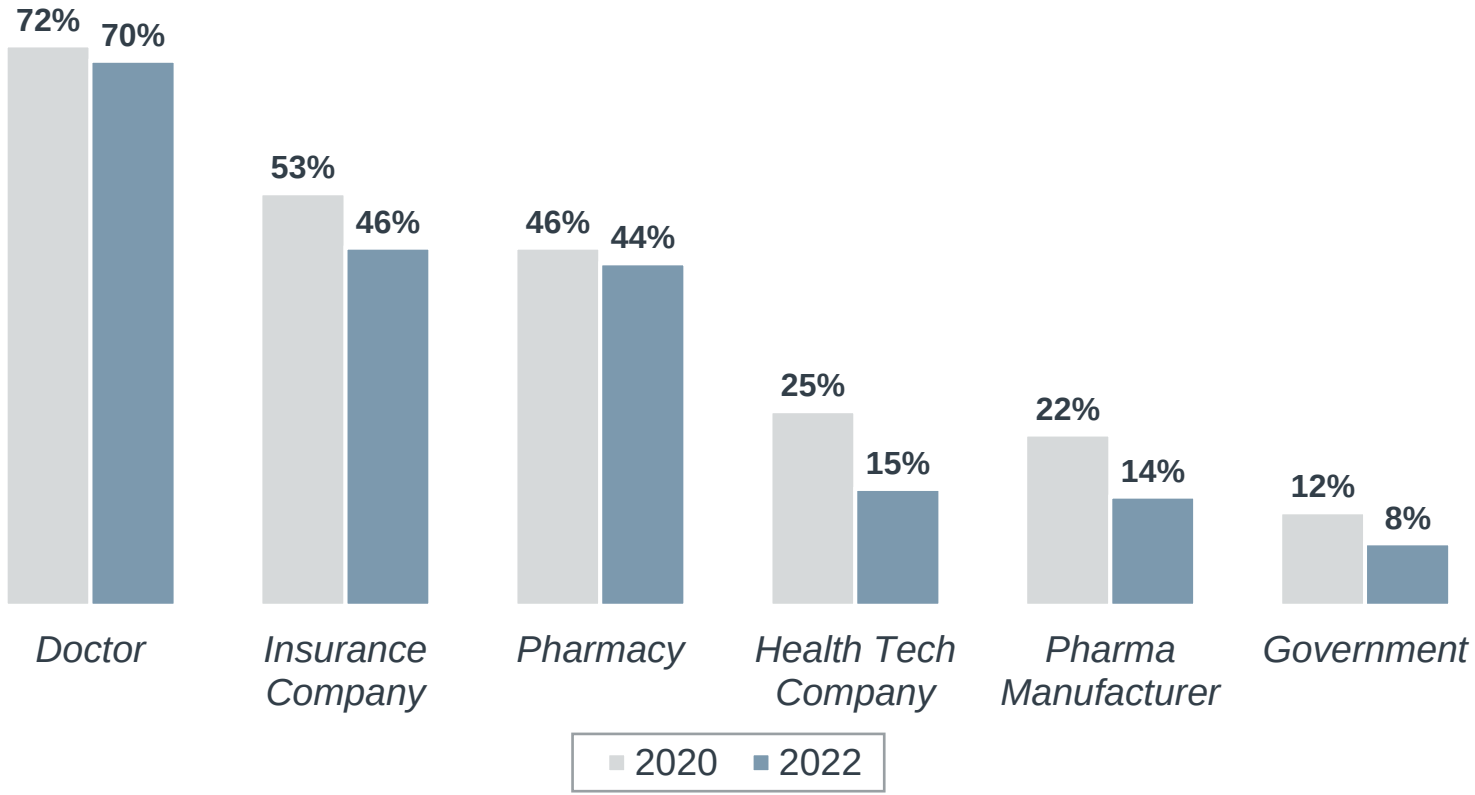
More patient-generated data, less patient trust

Percent of consumers who own a wearable device



Percent of consumers willing to share health data[1] with various stakeholders



1. Including medical records, test results, prescription drug history, genetic information, and physical activity data.

Source: "Consumer adoption of digital health in 2022: Moving at the speed of trust", Rock Health, Feb 21, 2023.

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Considerations for building and maintaining patient trust

For the healthcare ecosystem to **use patient data to improve care while making sure that patients trust with how their data is being used,** industry leaders consider:

Payers

How to avoid leveraging data in a way that leads to bias, and ultimately worse outcomes and higher costs for members

Care delivery

- Which third parties patients will trust providers sharing data with
- The minimal amount of patient data they can share that would still generate valuable results

Manufacturers

- What data is and is not HIPAA[1] protected, and how to respond if data breaches occur
- How the FTC[2] cracking down on selling data to third parties might impact revenue generation
- Giving patients a clear, tangible value proposition for sharing their data

1. Health Insurance Portability and Accountability Act.
2. Federal Trade Commission.

Advisory Board interviews and analysis.

GROUP DISCUSSION

Advisory Board

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